COLLEGIUM RAMAZZINI STATEMENT ON CHEMICALS CONTROL
A Call for Action to Protect Human Health

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The European Union (EU) is currently negotiating the renewal of the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) legislation. In the USA, a proposal has recently been made to strengthen current legislation enacted in 1976 that provides very weak requirements for testing of chemicals. An opportunity therefore exists to revisit the international needs and mechanisms for chemicals control.

Exposure to toxic chemicals at work, from contamination of food, drinking water, atmosphere, and consumer products leads to serious adverse human health effects, especially in vulnerable populations, such as pregnant women and children. However, most of the high-volume production chemicals have not been tested in detail for adverse effects, and prevention of chemically-induced disease. International collaboration on chemicals testing and control is therefore an urgent priority.

Because the number of chemicals that cause human exposures is very large, detailed test information will not realistically be obtained on all major pollutant in the near future. Thus, prudent measures must be instigated to manage the main pollutants in the absence of detailed risk assessment.

To deal with uncertainty in regard to chemical risks, the World Trade Organization already allows provisional measures "on the basis of available pertinent information". It thereby avoids serious delays in regulation when the evidence is insufficient for formal risk assessment. Similarly, the EU Treaty includes the precautionary principle, which facilitates protection against plausible health risks in the absence of scientific proof.

The Collegium Ramazzini urges the USA, the EU, the WTO and other international organizations and governments to adopt strong legislation to obtain toxicity test data on industrial chemicals and to protect public health and the environment against adverse effects of chemicals.

The Collegium recommends:

- Enforcement of new regulations that allows production and use of chemicals only if considered free of risks to human health;
- International agreement on methods for testing industrial chemicals for toxicity and for sharing the data;
- Inclusion of test methods to identify substances that cause endocrine disruption, neurotoxicity, immunotoxicity and other effects that are particularly hazardous during early development;
- Application of cut-off criteria as hazard triggers to eliminate the most hazardous industrial chemicals from consumer products and the environment;
- Strengthening of biological monitoring to document internal exposures of workers and the general population; and
- Support for targeted research that focuses on high-priority chemicals and key issues necessary to understand to provide better risk assessment and prevention.

Current safety testing is inadequate

The majority of industrial chemicals to which workers and consumers are exposed have not been adequately test for adverse effects on human health. The REACH legislation in the EU constitutes an important advance, as it requires producers and users of an estimated 30,000 chemicals in commerce in Europe to register them and provide information on their production, use, hazard and exposure potential. For chemicals identified as Substances of Very High Concern, REACH will allow their use only if explicitly authorized. However, delays have occurred, as responsible industries have not delivered the information needed in a timely fashion.[1]

Additional efforts are being mounted to assess in a more systematic way the toxicity of chemicals on the market. The voluntary High Production Volume (HPV) Chemical Challenge in the U.S. is developing basic screening information on the potential hazards of some 2,000 of the highest-volume chemicals in use. While only slow progress has been made, this effort represents an important, though small improvement, as the Toxic Substances Control Act (TSCA), the major US law enacted in 1976 to regulate chemicals, allowed the 60,000 chemicals in use at the time to be "grandfathered", i.e., to exempt them from any additional testing or meeting of any safety standard.

Canada's Domestic Substances List (DSL) Categorization, mandated by law in 1999, examined for the first time information available on the roughly 23,000 previously unassessed chemicals in current use. More than 4,300 of them were found to warrant further scrutiny of their potential risks.

Despite these initiatives, basic information on toxicity potentials of commonly used chemicals remains very patchy. Further, current toxicity testing is insufficient to identify the risks that affect vulnerable populations. Tests are generally carried out by administering the chemicals to experimental animals during adolescence, and the animals are then sacrificed and examined for toxic effects several months later. This traditional approach hampers the discovery of late consequences of exposure, such as cancer,[2] and makes it impossible to identify late consequences of developmental toxicity.[3] Thus, further testing will be needed to determine important and underestimated health risks, such as endocrine disruption, developmental neurotoxicity and similar effects that affect highly sensitive life-stages.

Early danger signals have been overlooked

Many classic technologies were initially hailed as beneficial and safe, but later found to cause great harm. Best documented are lead-containing additives used in paint and petrol, asbestos, polychlorinated biphenyls (PCBs), and the ozone-destroying chlorofluorocarbons (CFCs).[4] A recurrent theme in each of those episodes was that commercial introduction and wide dissemination of the new technology preceded any systematic effort to assess potential toxicity. As evidence emerged that occupational and environmental exposures were causing adverse effects on human health, vested commercial interests actively opposed efforts to examine and control exposures to these materials. Industries involved have used highly sophisticated disinformation campaigns to confuse the public, and they have directly attacked the scientists who called attention to the risks.[5]

The examples of missed early warnings underline a major dilemma of current risk assessment, where uncertainty rarely triggers stricter protection and most often is used as

an excuse not to regulate at all. Thus, early warnings are still ignored and not acted upon, while we are waiting for evidence to accumulate to a "convincing amount", which may require a very long time. At the same time, no concerted effort is made to obtain the missing information to inform the risk assessment.

For decades most chemicals have been presumed to be safe in the absence of clear evidence of harm. Regulatory agencies had to effectively prove beyond reasonable doubt that a chemical posed a risk before it could take any action to restrict its production or use. This passive approach provided little or no incentive for companies to submit or develop information. Any such activity might indeed increase the likelihood that evidence of harm would be uncovered, thereby triggering government action.

For a few substances (such as pharmaceuticals and pesticides) the approach was closer to 'presumed guilty until proven innocent'. For these products, producers had the burden of providing information to government deemed sufficient to demonstrate their safety, at least when used as intended (from: not so innocent). As a result, efforts to control exposures and to prevent injury have often been delayed, sometimes for decades.[6]

Outdated legislation

Because chemical pollution does not respect national borders, and because chemicals production and commerce are international, legal solutions must be found on an international scale. Such development is seriously held back by the lack of progress by major producers of chemicals. Thus, the Toxic Substances Control Act (TSCA) in the US today stands as a major stumbling block for chemical safety. In addition to "grandfathering" existing chemicals, the law requires that the U.S. Environmental Protection Agency (U.S.EPA) proves that a chemical is harmful before usage restriction can be considered. During the lifespan of the TSCA since 1976, the agency has required testing of only about 200 chemicals, and it has established limited restrictions on some uses of only five substances (PCBs, chlorofluorocarbons, dioxin, asbestos, hexavalent chromium).

For EPA to be able to take action to regulate use of a chemical under TSCA, the agency must demonstrate that the chemical presents or will present an unreasonable risk of injury to public health or the environment. Delays of years or even decades have occurred, as there is no deadline for completion of such risk assessments of chemicals. Although required by the law, manufacturers have provided little or no information on the potential health or environmental impacts of most chemical products. In addition, much of the information submitted is designated as confidential and must therefore be withheld from the public and even from state governments. While there are criminal penalties for knowingly disclosing such information, there are no penalties for making false safety claims, thus again providing a disincentive against submitting even the most basic information, such as how much of the chemical is being produced.

Legislation in many countries is outdated, too, in some cases almost non-existent. However, in order to manage the health risks associated with chemicals on a global scale, action is badly needed by the major chemicals production countries. Such action can usefully build upon the stricter requirements in regard to pharmaceuticals and also the current restrictions in regard to pesticides and biocides, although these regulations also need to be tightened.

The challenge

Workers are exposed to chemical risks, of which only a few hundred are regulated, and surveillance efforts are not aimed at identifying or preventing adverse health effects that may develop during several years of employment. The general population is also at risk. Following initial enthusiasm about genetic causes of disease, a recent estimate suggests that only 10 % of the burden of disease can be explained by genetic factors,[7] thus leaving about 90% to be attributed to environmental factors. Using current routine methods, the U.S. Centers for Disease Control and Prevention can reliably identify more than 200 industrial chemicals in blood and urine samples from the general population.[8] Similar efforts to document chemical exposures are anticipated in Europe. Most of these substances are thought to pass the placenta or to be excreted in milk, so that a mother shares her chemical burden with her child, who at the same times undergoes crucial development that is highly vulnerable to toxic damage.[9]

In regard to children alone, information on the costs to society due to the best known pollutants suggests annual expenses to society due to toxic effects are in excess of $50 billion in the US.[10] Costs to society due to effects in adults, such as cancer, cardiovascular disease, obesity, and other adverse effects add substantially to the costs, although no estimates are available. Highly-exposed workers constitute a particular risk group, who carries a high burden of chemically-induced disease. Additional costs carried by patients and families are often regarded intangible, but should not be ignored.

Existing mechanisms

Mechanisms already exist for chemicals control and protection of vulnerable population against chemical exposures. To deal with uncertainty in regard to chemical risks, the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) from 1995 allows provisional measures "on the basis of available pertinent information". It thereby avoids major delays in regulation when the evidence is insufficient to allow formal risk assessment.

A provision of the U.S. Food Quality Protection Act of 1996 instituted an additional 10-fold safety factor to protect sensitive populations such as infants and toddlers against food contaminants. Unfortunately, this provision has barely been used so far.

Similarly, the EU Treaty includes the precautionary principle, which facilitates protection against plausible health risks in the absence of scientific proof. However, although the framework therefore exists for prudent decisions under uncertainty, the necessary countermeasures have not emerged to make up for the impasse due to the existing delays in chemicals testing and risk assessment.[11] In general, the precautionary principle incorporates the necessary elements to form the bedrock of a new framework.[12]

Need for precaution

A new paradigm is needed to provide the necessary support for public health and investment in safe chemical use in the future. The major challenge is to secure that at least temporary decisions can be made in the absence of clear scientific documentation.

The key element of the precautionary principle is that it provides justification for acting in the face of uncertainty, as a tool for acting on the basis of early warnings. Under the precautionary principle, the burden of proof should therefore be shifted. Accordingly, technologies are no longer presumed safe simply because evidence of risk is unavailable.

Instead, safety must be documented. Existing chemicals production and usage must require scrutiny to determine the need for safeguards, and all new technologies should be properly examined for potential toxicity before commercial introduction.

Accordingly, the renewal of the REACH legislation must consider a new framework, where the approach is shifted to secure safety, rather than to detect risk. Thus, decisions should be based on hazard assessment that focuses on possible adverse effects on the most vulnerable population. This approach will require new test methods that assess the adverse effects during early development, such as endocrine disruption, neurotoxicity, and immunotoxicity.

In the U.S., the proposed Child Safe Chemical Act requires that new chemicals be tested and found safe for children before they are brought to market, that manufacturers prove the safety of the 62,000 chemicals "grandfathered in" without testing under TSCA thirty years ago if these chemicals are to remain in commerce, that the U.S.EPA develop a list of "priority" chemicals that will receive immediate attention, and that all of this information be regularly updated and made publicly available. This initiative is an important step in the right direction to secure chemical safety internationally.

Need for research

Progress in chemicals control and disease prevention will require research to understand better the risks and how they may be combatted. In the absence of incentives to study high-priority chemicals, much of the current academic research on environmental chemicals has focused on well-known hazards.[13] Mechanisms are needed to inspire and support science that will help risk assessments for hazards that are poorly understood and therefore need exploration to inform prevention efforts.

In more general terms, new issues in toxicology and environmental science need attention, especially the existence of low-dose toxicity that has been demonstrated for several industrial chemicals much below levels that were thought to be safe. The increased vulnerability during early development needs to be examined in greater detail, how it relates to different organ systems and the long-term consequences. Further, the so-called cocktail effect due to exposure to multiple contaminants needs to be taken into regard. Some of these questions can be addressed in experimental studies, but others will require prospective population studies, such as the US National Children's Study and related efforts in the EU and elsewhere.

While support for targeted research on these issues is a high priority, such investment should not be used as an excuse to delay necessary decisions on chemicals control. Such decisions will always remain temporary and will be subject to possible adjustment as new information emerges. It will be a tragic mistake to continue delaying prevention in the hope that science will soon provide complete guidance on how to protect human health.

The Collegium Ramazzini is an international scientific society that examines critical issues in occupational and environmental medicine with a view towards action to prevent disease and promote health. The Collegium is dedicated to the prevention of disease and the promotion of health. The Collegium derives its name from Bernardino Ramazzini, the father of occupational medicine, a professor of medicine of the Universities of Modena and Padua in the late 1600s and the early 1700s. The Collegium is comprised of 180 physicians and scientists from 35 countries, each of whom is elected to membership. The Collegium is independent of commercial interests.

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